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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/288,238	04/08/99	DRIZEN A	23842

HM12/0628

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EXAMINER	
HARRISON,R	
ART UNIT	**PAPER NUMBER**
1617	3

DATE MAILED: 06/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/288,238	Drizen et al
Examiner	**Group Art Unit**
Robert H. Harrison	1617

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *45-82* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *45-82* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

With the entry of the amendment filed as of April 8, 1999, claims 45-82 are in the case.

The Examiner respectfully requests applicants to submit copies of claims of all copending applications whether pending or allowed which may raise an issue of double patenting or obviousness double patenting since such applications may not be readily available to the Examiner for consideration of such issues.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,709,883.

Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no clear patentable line of demarcation between the issued claims and the instant claims since the instant disclosure defines the active drug can be an analgesic and one skilled in the art would immediately envisage opioid analgesics as within the generic "analgesic". If applicants traverse, then applicants are respectfully requested to clearly point out why opioid analgesics would not be contained within the "analgesics" recited in the instant claims. drop

Claims 45-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,897,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no clear line of patentable demarcation between the issued claims and the instant claims since there appears to be considerable overlap in structure. If applicants traverse, then applicants are respectfully requested to point out a clear line of patentable demarcation between the respective sets of claims. Keep

Claims 45-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of copending application Serial No. 08/825,121. Although the conflicting claims are not identical, Keep

they are not patentably distinct from each other because there is no clear line of patentable demarcation between claim 10 in the copending case and the subject matter covered by the instant claims since there appears to be considerable overlap in structure. Please note that the respective sets of claims both claim anaesthetics.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 45-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35, 38-42 and 44-52 of copending application Serial No. 09/004,631. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no clear line of patentable demarcation between the respective sets of claims in the copending cases because there appears to be considerable overlap in terms of the compositions set forth. If applicants traverse, then applicants are respectfully requested to point out a clear line of patentable demarcation since the Examiner is not of the position that such exists since the structures appear to overlap.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55, 65, 69, 73, 77, 81 and 82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for derivatives which are diclofenac sodium, diclofenac potassium, does not reasonably provide enablement for derivatives of diclofenac. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This disclosure only discloses these particular derivatives and no others. Since applicants have not defined what a derivative of diclofenac is with the exception of two specific salts of diclofenac, one skilled in the art would be forced to resort to undue experimentation in order to practice the invention as claimed.

Claims 45-70, 73, 77, 81 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The term "capable" in claims 45, 61 and 67 is a relative term which renders the claim indefinite. The term "capable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "capable" is vague and indefinite since it appears as though the composition is capable of future intended use.

In claims 55, 65, 69, 73, 77, 81 and 82, the term "derivative" is vague and indefinite since it is not clear what structures are encompassed thereby. In its broadest sense, a "derivative" could read on any molecular fragment of diclofenac however small and thus one skilled in the art would not be able to determine whether the claims are being infringed by the prior art. Further specificity or definition is deemed necessary.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or

on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-55, 57-65, and 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Sander et al. (U.S. Patent No. 5,356,629).

Sander et al. discloses a polymeric matrix which is suspended in an aqueous medium or can be diluted which contains the claimed mixture of polymers. See Examples 9 and 10 which reduce to practice the claimed mixture of polymers. Suitable drugs include antibiotics which are encompassed by the instant claims and specifically contemplated in their composition according to patentees such as antibiotics. See column 4, lines 51 et seq. The molar ratios as well as the overall amounts fall within the ranges as claimed and thus would be immediately envisaged as the instant invention is concerned. Please note that the instant claims do not exclude the polymer particles required by patentees. Future intended use as being capable of topical application would not distinguish over the composition of patentees since it would appear that such compositions are capable of topical application to treat pain. This position is taken because they are structurally overlapping those compositions set forth in the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 45-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leshchiner et al. (U.S. Patent No. 5,143,724).

Leshchiner et al. disclose biocompatible viscoelastic two-phase gel slurries wherein the first phase comprises hyaluronic acid and its salts (see column 3, lines 59-62). The second phase comprises cellulose derivatives such as carboxymethyl cellulose (CMC), hydroxypropylmethyl cellulose and hydroxyethyl cellulose (see column 4, lines 45-50). The solvent can be water. The concentration of hyaluronic acid can be from 0.15-5% by weight (see column 6, lines 61-64). The composition may contain drugs (see column 7, lines 60-65). Example 12 shows a composition comprising a 1:1 CMC-hylan gel (see column 18, lines 31-37). It would have been within the purview of one having ordinary skill in the art at the time the invention was made to select the claimed active given the clear suggestion of a generic teaching of any drug which can be used in the gels of Leshchiner et al. and thus absent a showing of superior results in a <u>particular</u>

drug, all drugs disclosed usable in the gels are viewed as equivalent for the purposes of Leshchiner et al.

Any inquiry concerning this communication should be directed to Robert H. Harrison at telephone number (703) 308-2422.

Robert H. Harrison
Primary Examiner
Art Unit 1617

RHHarrison:cdc
June 22, 1999